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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23117

7590

01/04/2011

NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 01/04/2011

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,638	12/22/2006	Barton Haynes	1579-1093	4199

TITLE OF INVENTION: NUCLEIC ACIDS ENCODING MODIFIED HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) GROUP M CONSENSUS ENVELOPE GLYCOPROTEINS.

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	04/04/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where n

ppropriate. All further ndicated unless correcte naintenance fee notificat		g the Patent, advance of terwise in Block 1, by (a	rders and notification a) specifying a new co	of m orresp	aintenance fees woondence address;	ill be and/or	mailed to the current (b) indicating a separ	correspondence address a rate "FEE ADDRESS" fo	is or
CURRENT CORRESPONDI		Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, mu have its own certificate of mailing or transmission.				2			
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APPLICATION NO.	FILING DATE		FIRST NAMED INVEN	TOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.	1
10/572,638	12/22/2006	•	Barton Haynes		•		1579-1093	4199	_
	N: NUCLEIC ACIDS PE GLYCOPROTEINS.	ENCODING MODIFIE			EFICIENCY VIR	RUS T	YPE 1 (HIV-1) GR	OUP M	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUE	E FEE	TOTAL FEE(S) DUE	DATE DUE	J
nonprovisional	YES	\$755	\$300		\$0		\$1055	04/04/2011	
EXAM	INER	ART UNIT	CLASS-SUBCLASS						
PARKIN, J	EFFREY S	1648	424-208100						
. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).  Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			(1) the names of u or agents OR, alter (2) the name of a s registered attorney 2 registered patent	2. For printing on the patent front page, list  1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  2) the name of a single firm (having as a member a egistered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is 3 isted, no name will be printed.				_	
PLEASE NOTE: Unl	less an assignee is identi h in 37 CFR 3.11. Comp	A TO BE PRINTED ON The field below, no assignee eletion of this form is NO	data will appear on th	ne pa g an a	tent. If an assigne ssignment.			ocument has been filed fo	- or
lease check the appropri	iate assignee category or	categories (will not be pr	rinted on the patent):		Individual 🖵 Co	rporati	on or other private gro	up entity 🔲 Governmen	ıt
a. The following fee(s) are submitted:  Issue Fee Publication Fee (No small entity discount permitted) Advance Order - # of Copies			<ul> <li>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</li> <li>A check is enclosed.</li> <li>Payment by credit card. Form PTO-2038 is attached.</li> <li>The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).</li> </ul>						
_ ~ .	<b>tus</b> (from status indicated s SMALL ENTITY statu	· · · · · · · · · · · · · · · · · · ·	☐ b. Applicant is no	long	er claiming SMAI	LENT	ΓΙΤΥ status. See 37 CF	FR 1 27(g)(2)	
NOTE: The Issue Fee and	d Publication Fee (if requ		d from anyone other th	_	-			e assignee or other party i	n
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10/572,638	12/22/2006	Barton Haynes	1579-1093	4199	
23117 7:	590 01/04/2011		EXAM	INER	
NIXON & VAN	DERHYE, PC	PARKIN, JEFFREY S			
	BE ROAD, 11TH FLO	OR	ART UNIT	PAPER NUMBER	
ARLINGTON, VA 22203			1648		
			DATE MAILED: 01/04/2011		

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 366 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 366 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)
Notice of Allowability	10/572,638 <b>Examiner</b>	HAYNES ET AL.
		7.11. 5.11.
	Jeffrey S. Parkin	1648
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this or other appropriate communic IGHTS. This application is subj	s application. If not included ation will be mailed in due course. <b>THIS</b>
1. $\boxtimes$ This communication is responsive to <u>the request for continuous</u>	ued examination filed 04 Augus	<u>t, 2010</u> .
2. The allowed claim(s) is/are 127-134, renumbered 1-8.		
3. Acknowledgment is made of a claim for foreign priority ur  a) All b) Some* c) None of the:  1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	be been received. been received in Application No cuments have been received in the communication to file a received to this communication to file a received.	o this national stage application from the
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give		
5. CORRECTED DRAWINGS ( as "replacement sheets") mus		
(a) Including changes required by the Notice of Draftspers		PTO-948) attached
1)  hereto or 2)  to Paper No./Mail Date		
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1		
each sheet. Replacement sheet(s) should be labeled as such in t		
<ol> <li>DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT</li> </ol>		
<ul> <li>Attachment(s)</li> <li>1. ☐ Notice of References Cited (PTO-892)</li> <li>2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>3. ☑ Information Disclosure Statements (PTO/SB/08),</li></ul>	6.  ☐ Interview Sumr Paper No./Mai 7.  ☑ Examiner's Am	I Date
/Jeffrey S. Parkin/ Primary Examiner, Art Unit 1648		

Application No.: 10/572,638 Docket No.: 1579-1093
Applicants: Haynes, B. F., *et al.* Filing Date: 12/22/2006

#### Examiner's Amendment

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

The application has been amended as follows:

- Please amend the TITLE to read as follows: NUCLEIC ACIDS ENCODING MODIFIED HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) GROUP M CONSENSUS ENVELOPE GLYCOPROTEINS.

#### Reasons for Allowance

The following is an Examiner's Statement of Reasons for Allowance: The claimed invention is directed toward nucleic acids encoding consensus HIV-1 group M Env sequences (CON-S). CON-S was obtained by aligning the consensus env sequences of group M subtypes (A-D, F-H, J, and K) from the 2003 Los Alamos sequence listing to obtain a parent sequence. The hypervariable regions (excluding V3) were generated through hand alignments of potential N-linked glycosylation sites and cysteine residues. The hypervariable loops tended to comprise a shorter range of lengths as compared to natural strains. The CON-S env gene was generated by converting amino acid sequences of CON-S to nucleotide sequences employing the codon usage of highly expressed human genes. HIV-1 gp140 Envs with deletion of the cleavage (C) site and fusion (F) domain were designated gp140ACF. The polypeptide encoded by the claimed invention

Application No.: 10/572,638 Docket No.: 1579-1093
Applicants: Haynes, B. F., et al. Filing Date: 12/22/2006

induced robust neutralization responses against multiple group M subtypes (e.g., B and C). Although the generation of HIV-1 consensus and ancestral sequences has been disclosed elsewhere, considerable variation in the methods employed in designing these sequences exists. The prior art fails to disclose the method utilized in the instant application to arrive at the claimed sequences. Accordingly, the prior art neither teaches nor fairly suggests the claimed invention. The amended claims accurately define the applicants' invention and are of such scope that the specification provides an enabling disclosure. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Zachariah Lucas, can be reached at (571) 272-0905. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing

Application No.: 10/572,638 Docket No.: 1579-1093
Applicants: Haynes, B. F., et al. Filing Date: 12/22/2006

System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/ Primary Examiner, Art Unit 1648

15 December, 2010